DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0498]

Compliance Program Guidance Manual 7371.009; Bovine Spongiform Encephalopathy/Ruminant Feed Ban Inspections; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance program guidance manual (CP) entitled ''Bovine Spongiform Encepholopathy/Ruminant Feed Ban Inspections.'' This CP is intended to assist investigators in determining compliance with the FDA regulation prohibiting the use of specified animal proteins in ruminant feeds (21 CFR 589.2000). The purpose of this regulation is to prevent the establishment and/or amplification within the United States of bovine spongiform encephalopathy (BSE), a fatal degenerative nerve disease of cattle.

DATES: Submit written or electronic comments on the CP at any time.

ADDRESSES: Submit written requests for single copies of the CP to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Copies of the CP also may be downloaded to a personal computer with access to the Internet. The CVM home page includes a link to the CP and may be accessed at *http://www.fda.gov/cvm*. Submit written comments on the CP to the Division of Dockets Management (HFA–305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:///www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this compliance program: Neal Bataller, Center for Veterinary Medicine, HFV–230, Food and Drug Administration, 7500 Standish Pl., Rm. E441, Rockville, MD 20855, 301–827–0163, e-mail: *nbatalle@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On August 4, 1997, the ruminant feed ban regulation in § 589.2000 (21 CFR 589.2000) became effective. This regulation prohibits the use of certain proteins derived from mammalian tissues in the feeding of ruminant animals. The regulation is intended to prevent the establishment and/or amplification within the United States of BSE, a fatal degenerative nerve disease of cattle.

BSE is the bovine form of a group of uniformly fatal neurological diseases known as transmissible spongiform encephalopathies (TSEs). BSE appears to be spread through the feeding to cattle of protein derived from TSE-infected animal tissues. Specifically, epidemiologic evidence gathered in the United Kingdom suggests an association between BSE and the feeding to cattle of protein derived from sheep infected with scrapie, another TSE. BSE represents a public health concern based on the possible connection between BSE and a form of human TSE, new variant Creutzfeldt-Jacob disease (nv-CJD), that is believed to have resulted from people eating ruminant tissues infected with the BSE agent. BSE has had a devastating economic effect on the livestock

industry in countries where it has been identified or suspected. BSE has not been diagnosed in the United States.

The regulation in § 589.2000 affects renderers, protein blenders, commercial animal feed manufacturers, distributors (including retailers), transporters of animal feed and feed ingredients, on-farm animal feed mixers, and ruminant feeders. Based on the acute need to prevent the entry and spread of BSE, FDA has set a goal of full compliance with the regulation. This CP is intended to assist in the conduct of inspections to enforce § 589.2000 and thereby minimize risk to human or animal health.

II. Significance of Guidance

This CP is being issued as a level 1 guidance consistent with our good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to provide guidance and instructions to both agency and state investigators in conducting inspections under § 589.2000 for preventing the introduction and amplication of BSE in the United States. Such guidance is presently not available. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. Comments will be considered by the agency in the development of future policy.

The CP represents the FDA's current thinking on the subject. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance document.

Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Copies of the CP may also be downloaded to a personal computer with access to the Internet. The CVM home page includes a link to the CP and may be accessed at *http://www.fda.gov/cvm*.

Dated: November 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S